



APRIL 15, 2008

## HEALTH ADVISORY

**This is an official**

### **CDC Health Advisory**

Distributed via Health Alert Network

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#### **CDC Alert on Adverse Effects Associated with Consuming “Total Body Formula” and “Total Body Mega Formula”**

The Centers for Disease Control and Prevention is working collaboratively with state health departments, the American Association of Poison Control Centers, and the U.S. Food and Drug Administration (FDA) on reports of adverse health effects following consumption of the dietary supplement “Total Body Formula,” and “Total Body Mega Formula” manufactured in the USA exclusively for Total Body Essential Nutrition, Inc. This dietary supplement has been found by FDA to contain hazardous levels of selenium (up to 200 times the label value) and chromium (up to 17 times the label value).

An FDA press release on April 9, 2008 detailed information regarding the level of selenium in the product (<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01818.html>). FDA is advising consumers to stop using “Total Body Formula” in flavors Tropical Orange and Peach Nectar and “Total Body Mega Formula” in the Orange/Tangerine flavor and discard them by placing them in a trash receptacle outside of the home. “Total Body Formula” products are sold in eight-ounce and 32-ounce plastic bottles. “Total Body Mega Formula” is sold in 32-ounce plastic bottles. Products with the following lot numbers should be discarded: Total Body Tropical Orange with lot numbers 4016801, 4024801 and 4031801; Total Body Peach Nectar with lot numbers 4016802 and 4031802; and Total Body Mega Orange/Tangerine with lot number 4031803.

As of April 11, 2008, 91 adverse reactions have been reported from Florida, Georgia, Kentucky, Pennsylvania, Tennessee, and Virginia health departments. The American Association of Poison Control Centers and the FDA report additional exposures in other states.

Total Body Essential Nutrition, Inc reportedly distributed this product to 16 states (Alabama, California, Florida, Georgia, Kentucky, Louisiana, Michigan, Missouri, New Jersey, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, and Virginia), and also sells its products over the Internet.

#### Clinical description of selenium toxicity

Excessive intake of selenium is known to cause the following symptoms: significant hair loss, muscle cramps, diarrhea, joint pain, fatigue, loss of finger nails and blistering skin.

#### Clinical description of chromium toxicity

Excessive intake of chromium may result in the following symptoms: renal failure, elevated hepatic enzymes, thrombocytopenia, hemolysis, changes in thought processes, gastrointestinal disorders, chest pain, erythema/flushing/rash, dizziness, headache, agitation, and rhabdomyolysis.

#### Case definition

Individuals presenting with two or more of the following symptoms that occurred within two weeks of ingesting a dietary supplement manufactured in the USA exclusively for Total Body Essential Nutrition, Inc: hair loss, muscle or joint pains, fingernail discoloration or changes, headache, foul breath, weakness, gastrointestinal symptoms (such as nausea, vomiting, diarrhea or abdominal pain), rash, oliguria/anuria or abnormal renal function tests, jaundice or abnormal liver function tests, anemia or hematological changes.

CDC requests that consumers and clinicians who encounter patients with symptoms consistent with selenium and/or chromium poisoning report these cases to their local poison control center (PCC) at 1-800-222-1222. Medical personnel are available at PCCs to provide specific medical management advice and will make appropriate referral to state and local health authorities.

Health care professionals and consumers are also encouraged to report adverse events to the FDA's MedWatch program at 800-FDA-1088 or online at [www.fda.gov/medwatch/how.htm](http://www.fda.gov/medwatch/how.htm).

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- *Health Advisory provides important information for a specific incident or situation; may not require immediate action.*
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This message is being sent to local public health units, clinics, hospitals, physicians, tribal health, North Dakota Nurses Association, North Dakota Long Term Care Association, North Dakota Healthcare Association, North Dakota Medical Association, North Dakota EMS Association and hospital public information officers.

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